

**REMARKS**

Claims 42-70 are pending in the subject application. Applicants herein cancel claims 43, 44 and withdrawn claims 46-54 without prejudice or disclaimer. Applicants herein amend claims 42 and 45. Support for amended claim 42 can be found in the specification at, *inter alia*, page 39, line 30 to page 40, line 16. Claim 45 was amended to depend from claim 42 rather than canceled claim 44. Applicants maintain that the amendments to claims 42 and 45 raise no issue of new matter. Accordingly, upon entry of this Amendment, claims 42, 45 and 55-70 will be pending and under examination in the subject application.

**Double Patenting Rejection**

The Examiner provisionally rejected claims 42-45, 55-65 and 70 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-3 and 16 of copending U.S. Serial No. 08/905,709 and claims 36, 39, 40 and 53 of copending U.S. Serial No. 09/498,459.

In response to the rejection of claims 43 and 44, applicants note that those claims have been canceled herein. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of claims 42, 45, 55-65 and 70, applicants will respond to this rejection once it is no

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longer provisional.

**Rejections under 35 U.S.C. §102(b)**

The Examiner rejected claims 42-45, 55, 57-61, 63-68 and 70 under 35 U.S.C. §102(b) as allegedly anticipated by WO 97/26913 ("the '913 application").

In response to the rejection of claims 43 and 44, applicants note that those claims have been canceled herein. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of claims 42, 45, 55, 57-61, 63-68 and 70, applicants respectfully traverse.

Claim 42, as amended, provides a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's Disease, in a subject. This method comprises administering to the subject a binding-inhibiting amount of a compound comprising a fragment of sRAGE, which compound is capable of inhibiting binding of the  $\beta$ -sheet fibril to RAGE so as to thereby prevent and/or treat the disease.

In order for the claims to be anticipated by the '913 application, this reference would have to teach each and every element thereof. The '913 application fails to do so.

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Specifically, nowhere does the '913 application teach a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's Disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a *compound comprising a fragment of sRAGE*.

The Examiner also rejected claims 42-45, 55, 57-68 and 70 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 5,864,018 ("the '018 patent").

In response to the rejection of claims 43 and 44, applicants note that those claims have been canceled herein. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of claims 42, 45, 55, 57-68 and 70, applicants respectfully traverse.

Like the '913 application, the '018 patent also does not teach a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's Disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a *compound comprising a fragment of sRAGE*.

Accordingly, applicants maintain that claims 42, 45, 55, 57-68 and 70 satisfy the requirements of 35 U.S.C. §102(b).

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**Rejection under 35 U.S.C. 103(a)**

The Examiner also rejected claims 42-45 and 55-70 under 35 U.S.C. §103(a) as allegedly obvious over the '018 patent, in view of Lilley, et al. and Kelley.

In response to the rejection of claims 43 and 44, applicants note that those claims have been canceled herein. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of claims 42, 45 and 55-70, applicants respectfully traverse.

In order to find the subject application obvious over the '018 patent in view of Lilley, et al. and Kelley, the prior art references, in combination, must teach or suggest all the elements thereof, and create both a motive to combine and a reasonable expectation of success. The '018 patent, Lilley, et al. and Kelley fail to do this.

As discussed above, nowhere does the '018 patent teach or suggest a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's Disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound comprising a *fragment of sRAGE*.

Lilley, et al., which teach that diabetes mellitus is associated with delayed wound healing, and Kelley, which

teaches prion diseases result from  $\beta$ -sheet fibril formation, fail to cure this deficiency, in that combined, they also fail to teach or suggest a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's Disease using a compound comprising a *fragment of sRAGE*.

In addition, applicants note that the subject application is based, at least in part, on the unexpected discovery that "RAGE serves as a magnet to tether A $\beta$  fibrils to the cell surface...[thus causing] receptor-mediated activation of the MAP kinase pathway... Furthermore, incubation of initially soluble A $\beta$  with RAGE accelerates fibril formation... RAGE binds fibrils composed of amyloid A, amylin, and prion-derived peptides, though the receptor does not interact with the soluble subunits." (page 4, lines 4-15 of the specification).

Applicants maintain that the cited references in no way teach or suggest applicants' unexpected findings, and likewise do not teach or suggest the resulting claimed invention.

Accordingly, applicants maintain that claims 42, 45 and 55-70 satisfy the requirements of 35 U.S.C. §103(a).

### Summary

In view of the above remarks, applicants maintain that the pending claims are in condition for allowance.

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Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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